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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/980,697

08/14/2002

Ajay Kumar Luthra

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EXAMINER

YOUNG, MICAH PAUL

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 03/10/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/980,697

Applicant(s)

LUTHRA ET AL.

Examiner

Micah-Paul Young

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 39-65 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 39-65 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

DETAILED ACTION

Acknowledgment of Papers Received: Information Disclosures Statement dated 12/12/03 and 07/09/04.

Claim Objections

1. Claims 40, 42-48, 50-65 objected to because of the following informalities: The claims are misnumbered, and improperly dependent from canceled claims. For the purposes of prosecution, the claims will be prosecuted as if they were dependent from claim 39. Appropriate correction is required.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 39, 41, 43, 45, 47-54, 56-60 and 63 are rejected under 35 U.S.C. 102(b) as being anticipated by Olstein (USPN 5,142,010 hereafter '010). Claim 39 is drawn to a polymeric material comprising an infection resistant biguanide compound. Claims 41 and 43 are drawn to a medical device comprising such a polymeric device. Claims 45, 47-54 and 56-60 are drawn to a method of making such a device. The '010 patent discloses a polymeric biocidal compound. The biguanide polymers of the invention are useful in medical, food preparation and personal care applications (abstract). The biguanide composition can be incorporated in functional polymers useful in forming films, fabrics, fibers aqueous dispersions, and solvent-based solutions (col. 4, lin. 32-39). Polymerized biguanide compounds of the invention contain vinyl polymerization

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groups, which can be copolymerized with various unsaturated monomers including alpha olefins, ethylene and propylene (col. 9, lin. 48-60). The reactive sites include carboxyl and/or amino groups (col. 5, lin. 29-65). These disclosures render the claims anticipated.

5. Claims 39-45 and 63-65 are rejected under 35 U.S.C. 102(b) as being anticipated by Ogunbiyi et al (UPSN 4,537,746 hereafter '746). Claims 39 and 40 is drawn to a polymeric material comprising an infection resistant biguanide compound. Claims 41 – 44 are drawn to a medical device comprising such a polymeric device. Claims 45, and 63-65 are drawn to a method of making such a device. The '746 patent discloses biocidal biguanide polymers (abstract) in conjunction with medical devices. Biguanide residues include chlorhexidine, and are used to disinfect polymeric surfaces such as contact lenses (col. 5, lin. 11-20; examples). These disclosures render the claims anticipated.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 39-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combined disclosures of Olstein (USPN 5,142,010 hereafter '010) and Stockel (USPN 4,537,746 hereafter '746). The claims are drawn to a polymeric material, and medical device comprising the material and a method of making the medical device. The polymeric material comprises an infection resistant biguanide compound. The biguanide compound is a residue of chlorhexidine or polyhexanide.

4. As discussed above the '010 patent discloses a biocidal biguanide polymeric material with vinyl unsaturated reactive sites, that was useful for medical purposes. However, the reference is silent to the specific biguanide residue. However the application of specific residues is well within the level of skill in the art to include chlorhexidine since the aim of the polymer is to resist infection.

5. The '746 patent discloses biguanide polymers (abstract) in conjunction with medical devices. Biguanide residues include chlorhexidine, and are used to disinfect polymeric surfaces such as contact lenses (col. 5, lin. 11-20; examples). An artisan of ordinary skill would have been motivated to produce the residues of '746 by the methods of '010 in order to form an effective biocidal polymer useful for medical devices.

6. With these things in mind one of ordinary skill in the art would have been motivated to produce the residues of '746 with the methods of '010 in order to produce an effective polymer coating for medical devices. As suggested in '746 the chlorhexidine is coated to the contact lens after application, and '010 produces suitable coating or dripped covering for medical devices. It would have been obvious to a skilled artisan to combine such teachings and suggestions with an expected result of a biocidal polymer capable of treating and/or preventing bacterial infection.

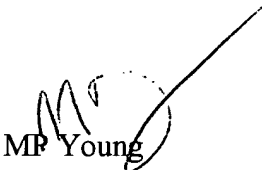
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Correspondence


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Micah-Paul Young whose telephone number is 571-272-0608. The examiner can normally be reached on M-F 7:00-4:30 every other Monday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


MP Young

Micah-Paul Young
Examiner
Art Unit 1615


THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600